RECOMMENDATIONS FOR REMEDIES*

SAMUELO, THIER, M.D.

David Paige Smith Professor and Chairman
Department of Internal Medicine
Yale University School of Medicine
New Haven, Connecticut

Today I have heard some of the best minds in American medicine fail to agree on the definition, magnitude, or etiology of our problem, and now I am asked how to solve it. Lack of agreement makes life easier for me, because in the absence of accepted interpretations of data, I can deal simply with policy and philosophy. However, unless we begin to separate the problems of care and education from those of research and clinical investigators, we shall get nowhere. I shall focus on the diminishing number of clinical investigators.

I would emphasize two points. One, data clearly indicate a drop-off in the numbers of individuals entering careers in clinical investigation.^{1,2} The more optimistic data we have seen today³ are projections and bets on what may occur in the next decade. We had better deal with the realities of the present situation and not comfort ourselves with projections of medical manpower in 1990. Certainly, the past decade should have taught us just how inaccurate projections of medical manpower can be.

By now all must be conviced that whatever else the academic medical center is, it is in trouble. The trouble is that it is unstable, that its future is unpredictable. In times of metastability, organizations that previously seemed monolithic and immovable may become amenable to change and improvement. In approaching the problems besetting academic medical centers, we want to protect what is best, to improve what is weak but essential, and to discard what is inferior or unnecessary. We should aim not to protect the status quo but to innovate and to create a more understandable, efficient, and effective medical center. The center and its academic faculty should pursue diverse and stable means of support, while placing greater values on evolution and advance than on physical and economic growth.

At the heart of academic medical centers is a scholar creating and transmitting new knowledge. The scholarly academic clinician has a unique position in this community of scholars. Being charged with investiga-

^{*}Presented as part of a Symposium on The Academic Physician: An Endangered Species held by the Committee on Medical Education of the New York Academy of Medicine October 10, 1980.

tion of human disease, a clinical investigator is a two-way conduit for research. In one direction, basic science information passes into clinical use; and, in the other direction, clinical observations go back to stimulate basic research. An academic physician has a critical role in educating future physicians and in developing and testing better ways for those physicians to practice. The presence and enthusiam of a cadre of clinical investigators also serves as a model that stimulates students, residents, and fellows to perpetuate the species. If a species in difficulty can first be regarded as threatened, then endangered, and finally extinct, it seems clear that the species called clinical investigator is now somewhere between threatened and endangered, but is unlikely ever to become extinct. The species has a life cycle that begins in premedical education and continues through medical school, residency, fellowship, and faculty phases: faculty members then stimulate students to begin the cycle again. If too few enter the cycle, if too many drop out along the way, or if the opportunities for full development during the faculty phase are inadequate, the species will not flourish. Therefore, well meant but simplistic remedies will be ineffective if directed at only one step in this cycle. Keeping the entire continuum in mind, we can examine remedies to improve diverse features of atmosphere and support.

The atmosphere that affects the development of clinical investigators contains social and institutional components. Society—through federal programs, foundation support, specialty board requirements, and media presentations—has indicated clearly that the development of high quality primary comprehensive health care is now the first priority of medical education. The message and orientation are hardly inappropriate, but they have been developed using ideas of competition rather than cooperation—and what has lost in the competition is academic medicine. Policy makers have forgotten that the advance of high quality clinical care requires not only a strong academic medical base, but a symbiotic relationship between academic physicians and practicing physicians. Society must become again mindful of this positive interaction and must also recognize that the cost of medical research, which is a minute fraction of the cost of medical care, is not the reason that the cost of care is rising so steeply. Some remedies suggested for these problems are as follows:

We need more effective methods to communicate the role of academic medicine to both the public and private sectors. These efforts should occur at all levels but should certainly involve the Association of American Medical Colleges, major research organizations, and the medical schools.

482

In addition, as the plight and importance of academic medical centers become evident, the private sector could be asked to provide support from its communication and lobbying skills.

Private foundations should re-examine their accomplishments and, future goals in the health field. Some of their attempts to alter the numbers and types of physicians have been eminently successful, so successful, in fact, that the contributions of private foundations are now dwarfed by federal funds. In view of this success, the foundations might reappraise the impact of their single-minded approach to supporting health care programs in lieu of supporting biomedical research. The previous message transmitted by the foundations about the importance of health care delivery may have been more important than the dollars. Perhaps it is now time to reconsider and to modify that message.

The medical specialty boards, particularly internal medicine and pediatrics, must continue to monitor the impact of their policies on the development of research careers. Even a modest increase in the flexibility of board requirements to permit attempts at careers in research would be important.

Even more important than these external aspects of society is the atmosphere of the academic institutions themselves. It is not possible for all medical schools to be research intensive. Those schools whose faculty wish to be research intensive should develop admission criteria that stress research potential and experience. These schools should also be the seats of M.D.-Ph.D. programs, and should put some institutional support into such programs. Advisory programs should be developed to nurture student research interest, and the curriculum should be modified to expand time for investigative experience. Residency training programs should permit more flexibility to absorb and continue the development of M.D.-Ph.D. students and others with proved research talent. Fellowship programs should provide at least two years of research in addition to time in clinical training. Most important, however, faculty members interested in clinical investigation must be given the same kind of protection of time, opportunity for advancement, and access to institutional resources that are provided to basic scientists. As long as clinical investigators are seen as capable of using clinical practice to generate their own plus additional institutional support, they will receive less of institutional resources, particularly at private schools. They will spread themselves too thinly to maintain outstanding scholarship and they will ultimately see their source of influence in the medical center as being derived from their clinical income. Departments with the largest clinical incomes may well become the least scholarly. It is possible that a reduction in the size of the clinical faculty, a reduction in the size of basic science faculty, and a redistribution of institutional resources may be necessary to bolster clinical science. This scenario would represent the most extreme remedy, but it is presented to focus attention on the need to reevaluate clinical academicians within today's academic centers.

Those academic physicians who function primarily in teaching and patient care usually do not have the same access to tenure appointments as those doing laboratory research. In fact, many schools have developed "clinical tracks" without tenure in parallel to the traditional "academic tracks" with tenure. Because traditional tenure is less available to *clinical* academicians, schools must develop attractive late career alternatives in administration, practice, etc. for these individuals. Without evidence that a clinical investigator has the opportunity for growth and security why would any bright young physician continue in academic clinical medicine?

Even if the societal and institutional atmosphere could be made favorable, financial support would still be needed. Support that in the pre-World War II era was modest and came largely from private sources shifted in the past 35 years to predominantly federal sources. In the past few years, however, private support has begun to return to universities, particularly to private schools.

Viewed in perspective, the federal support, which has dwarfed private support, particularly in the last three decades, has had some major benefits and some serious drawbacks.

Under the continuing authority of Section 301 of the Public Health Service Act, the National Institutes of Health (NIH) has supported medical research at a level unprecedented in history and has made the United States, until recently, the unchallenged world leader in biomedical research. This support, however, also stimulated an unplanned growth of medical school faculties and facilities without any concomitant long-term planning for alternatives to this support. Schools became dependent upon federal funds and then vulnerable to federal initiatives in admission policies, in curriculum content, and in other adminstative operations. As the federal support grew, pressures for accountability grew. Because universities, in the name of academic freedom, opposed almost all accountability programs, the programs developed without cooperation or leadership from the universities, and were installed over the protests of the investigators and the universities. Finally, special interest groups began to dictate the distribution of research dollars, e.g., the war on cancer, programs for the control of heart disease and stroke, etc. We have now arrived at a point where the 484 S.O. THIER

system of accountability is beyond the ken of most investigators; the federal administrative structure is bewildering; and both houses of Congress are attempting to gain more oversight of the National Institutes of Health. What can be done?

We must recognize that we are critically dependent upon the National Institutes of Health. Even if drastically reduced, these funds would still represent the major source of support for biomedical research. We should therefore argue for the greatest flexibility in the funding of the Institutes while recognizing that some form of increased congressional surveillance is inevitable. Certainly, if Congress insists on greater surveillance, a supervisory president's council would seem far preferable to a periodic reauthorization mechanism.

Academic physicians must realize that accountability is a responsibility incurred by accepting federal funds. Although not an intrusion on our academic freedom, accountability should not create excessive regulation. We in the academic medical community have not used our talents to develop mechanisms of accountability that would seem rational, that would feed into a trimmed down federal and National Institutes of Health bureaucracy, that would be satisfactory to the public. Such efforts would certainly be in our own enlightened self interest.

If we can develop reasonable mechanisms of accountability for the use of research funds, we should resist coupling of research support to other items in the federal agenda.

Many specific recommendations could be made to help stabilize federal support of research and research training. I will at this time simply state that such stabilization is the overriding goal. An important additional goal is to attract sufficient new entrants into training for academic careers so that after natural attrition has occured the number and quality of those joining faculties will be adequate to meet national needs.

One victim of the enormous growth of National Institutes of Health support in the last three decades was interaction between universities and the corporate sector. When private support of medical research fell as a percentage of all such support, our relationships atrophied and communication channels and common languages were lost. We in the academic medical centers lost diversification of our support, and the corporate sector lost ready access to sources of new information, consultative expertise, and the opportunity to join in common cause with private universities to pursue goals that might be suspect if pursued by the corporations alone. Finally, the corporations did not wish or did not have the opportunity to avail

themselves of resources that they could not have reproduced for many times the cost of access. The importance of the interface between academic medical centers and the corporate sector is obvious for the pharmaceutical industry, the insurance industry, and for biomedical engineering. That the food industry would wish to see the development of nutritional science is also evident. The importance of academic physicians to these areas is obvious and has been supported, particularly by groups such as the Pharmaceutical Manufacturers Association. Of interest is the recent heavy investment of the petrochemical industry in private universities. However, when one notes the critical importance of toxicology, clinical epidemiology and environmental health, and the use of recombinant DNA mutants in that industry, their interest is easily understood.

What can the private sector do to support academic medicine?

Current support mechanisms such as the Pharmaceutical Manufacturers Association funding of developing faculty members should be expanded. This type of specific industry support should be adopted by other groups in the private sector, such as the insurance industry, the food industry, and corporations that produce biomedical equipment.

The private foundations should develop programs that legitimize careers in academic medicine. Evidence that academic medicine and health care delivery are both essential to our health care system can be announced with only a modest investment. The Hartford Foundation has begun one such program.

Models of interaction between the corporate sector and academic medical centers should be developed. Initial attempts at such interactions have occurred, for example, between Monsanto and Harvard and between Yale and Miles Laboratories. The development of a few other similar programs could serve a critical leadership role by defining the advantages to both participants, the sources of friction and tension in such arrangements, and the accommodations to be reached to serve the needs of academia and the corporate sector. If these model ventures are successful, the models can be expanded.

Re-establishment of university-business ties has obvious potential benefits to both parties. but also raises serious concerns, some of which were recently presented in a thought-provoking article by Nobel and Pfund.⁴ Some of the issues they raise require discussion.

Government support is directed theoretically by social need and is subject to public scrutiny, thereby assuring access to the results of research and fostering academic freedom. Support from industry, on the other hand, is

486 S.O. THIER

held to be motivated by the need to show a profit and may require secrecy in the handling of results of research, thereby acting counter to academic free expression. This concern states the extremes of good and bad to make a point. In fact, the government is not an efficient instrument that recognizes social need and directs resources to meet that end. Rather, it is a cumbersome bureaucracy that responds to political pressures and special interest groups, and that is capable of unilateral abrogation of an agreement to support research. Industry, on the other hand, is quite capable of supporting efforts that have intrinsic social value while being profitable, and can be held to a contract. These contracts can attempt to protect public interest, freedom of information, etc. Modern pharmaceutical advances and much of the biomedical technology now in use were developed by the private sector. In addition, industry can certainly endow nonprofit activities with no strings attached, such as endowed chairs in medical schools.

The pressure of private support will subtly influence faculty members and institutions to support positions favorable to industry. Because faculty members are often the experts who provide data and opinion upon which regulatory processes are based, this type of influence may work against the public interest. This argument requires extensive discussion within medical schools and constant attention to its possibility. However, it is quite possible that universities and industry may have common cause in combatting excessive regulation. In fact, excessive regulation by federal bureaucracy may actually work against the public interest. I believe that some agreement as to what constitutes the public interest would be needed to judge the impact of the growing tension between government regulation on the one hand and the kind of freedom available to universities and industry on the other.

Since academic medical centers have been developed largely with public funds, they represent national resources. When industry buys into these centers, it obtains the benefits of public-fund-developed resources that industry could not have afforded at anything approaching what it will actually invest. Although this concern also requires much discussion, it can be noted that the government theoretically received a fair or even excellent return on their health research dollars; evidence has been assembled to support this contention. And industry presumably pays taxes and contributes to federally supported efforts. Thus, institutions have returned to the government and to the public the advances of medical science for which they were paid. It is by no means clear that either grantor or grantee in federally funded research came out ahead on the balance sheet. It is clear that industry contributed significant amounts to the public funds which supported the medical centers.

A somewhat different, but to me more important, concern is the responsibility of private institutions to innovate and create according to their talents and not according to federal dictate. If private institutions do not maintain their independence of direction, then presumably they lose their reason for existing.

To put the interaction between the private sector and university in perspective, however, I do not suggest a substitution of private support for federal support. Rather, I propose that a combination of the two sources of funding be used to provide a diverse and therefore more stable means of support. It also seems to me that the more diverse the base of support, the less opportunity any single funding source has to influence the direction of academic research.

In summary, I have recommended that academic clinical physicians be recognized as the critical connection between basic science and the development of new forms of diagnosis and therapy. The value and nearly unique role of these individuals within the health care system must be emphasized. and the emphasis must be supported by the actions of academic medical organizations, medical schools, foundations, specialty boards, and the media. The National Institutes of Health must be recognized for their highly successful achievement in the support of productive medical research. Efforts must be undertaken to maintain continuity of its functions and to ensure stability of its support. In dealing with National Institutes of Health support, medical schools must distinguish between accountability, which is our responsibility, and excessive regulation, which has become the bane of our existence. It is important to recognize that our failure to develop rational accountability mechanisms has fueled the regulatory fervor and has helped to create the now bewildering bureaucracy. Finally, I have suggested that we explore opportunities for renewed interactions between academic medical centers and the private sector. Although important caveats can be raised about those interactions. I believe we should pursue model interactions with those cautions clearly in mind.

REFERENCES

- Wyngaarden, J.B.: The clinical investigator as an endangered species. N. Engl. J. Med. 301:1254-59, 1979.
- Clinical Research Manpower. The Report of the ad hoc Committee on Clinical Research Training of the Association of American Medical Colleges. February 1980.
- Petersdorf, R.G.: Academic medicine: No longer threadbare or genteel. N. Engl. J. Med. 304: 841-43, 1981.
- 4. Noble, D.F. and Pfund, N.E.: Business goes back to college. *Nation*, p. 1, 246-52, September 20, 1980.